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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,058	03/15/2005	Wilhelm Scherze	23242	9013
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EXAMINER HOBBS, MICHAEL L				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,058

Applicant(s)

SCHERZE ET AL.

Examiner

MICHAEL L. HOBBS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3/MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/16/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Regarding claim 1, the phrase "or the like" on in the instant case "like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).
4. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6-8 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Banes (U.S. 6,586,235).
7. Banes teaches a cell culture device for monitoring fluid induced shear on cultured cells. Regarding claim 1, Banes discloses a cell culture device (**cell culture chamber**)

that has bores connected to the device that allows nutrients and air to pass through the device (Abstract, col. 2 lines 11-13, Fig. 12). Also, there is a membrane fixed between the base and the body of the culture device used to cultivate cells (**a membrane plate with a membrane serving to accommodate at least one cell culture**) (col. 2 lines 5-7, Abstract, Fig. 12). The device of Banes also teaches a port that is in fluid communication with the bores for delivering fluid, i.e. nutrients to the membrane (col. 2 lines 18-22) (**channels for supplying liquid, gassing and sensor connection**). Also, Banes discloses that the membrane is transparent (col. 6 lines 13-14) but, includes an insert member (Fig. 1 element 80) that supports the membrane and creates flow chamber underneath the membrane (col. 5 lines 29-32) (**transparent glass pane which is placed on one side of the membrane plate**). Also, a member (Fig. 1 element 64) is configured to allow the device to be placed on the objective of a microscope (col. 5 lines 6-7) (**transparent glass pane which is placed on one side of the membrane plate**). Also, a cover (Fig. 1 element 50) such as a glass microscope slide (**cover plate**) is placed over the gasket on the opposite side of the membrane (col. 4 lines 51-52) and it is inherent for a microscope slide to be transparent in order to allow light from a microscope light source to **illuminate[ing] the inside of the cell culture chamber**. For claim 2, the support base of Banes is located underneath the membrane (**transparent glass pane is fixed on the membrane plate in the area of the underside of the membrane plate**) (Fig. 1). For claim 3, Banes discloses that the glass microscope slide (**cover plate**) is on top of the culture device (Fig. 1) (**forms a cell culture chamber cap**) that inherently has a **integrated transparent glass pane**

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which is fixed to the device by conventional clamping means (col. 4 lines 62-63).

Furthermore, these conventional clamping means allow the cover slide to be removed (**cap being fixed in a releasable manner**). Also, for claim 4 the support member and cover slip of Banes **show an opening for the accommodation and fixation of the respective glass pane** (Fig. 1 elements 50, 10 & 64). Regarding claim 6, the device of Banes includes an O-ring (**retaining ring**) that is clamped with the membrane between the base and body of the cell culture device (col. 5 lines 18-20). For claim 7, Banes includes a gasket (**joint ring**) to help seal the cover slip to the culture device (col. 4 lines 49-51, Fig. 1 element 40) which performs the essential function of the joint ring in sealing the chamber to maintain a sterile environment. For claim 8, Barnes discloses that air is pulled through the device due to an applied vacuum that is used to help seal the cover slip onto the gasket (**constant continuous gassing by a means of suitable compartmentalization of the cell culture chamber via the respectively assigned channels**) (col. 4 lines 56-58). Regarding claim 11, the membrane of Banes is a gas-permeable membrane (**gas-permeable bio-foil**) (Abstract).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banes (U.S. 6,586,235) in view of Shanks (U.S. 4,810,658).

12. For claim 5, Banes does not mention that the **glass pane is a sapphire glass pane**.

13. Shanks discloses a photometric instrument that is used for optical analysis of samples on a microscope slide. Furthermore, for claim 5, Shanks discloses a slide that is made of glass, silica, inorganic crystal (eg. sapphire) or a plastic material (col. 3 lines 35-38). Therefore, it would have been obvious to one of ordinary skill in the art to

employ the sapphire slide as suggested by Shanks within the teachings of Banes to allow light to pass through the sample for optical testing. The suggestion for doing so at the time would have been in order to allow light from the liquid sample to emerge at different angles off-axis from the slide for the optical testing (Abstract).

14. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banes (U.S. 6,586,235) in view of Loeffler et al. (U.S. 6,673,620).

15. Banes remains silent regarding the **integrated heating for the cell culture system**. Also, Banes makes no mention that the heating element is electrical. For claim 9, Banes does teach the use of a support structure or insert (**retaining plate**) that is pressed against the O-ring in order to hold the membrane in place (col. 5 lines 15-16). The membrane is clamped (**supported**) between the rim of the body and the ledge of the insert (Fig. 1 element 80).

16. Loeffler teaches an in situ hybridization (ISH) cell that is used to observe fluid exchange on a microscope slide. For claim 9, Loeffler discloses that a heater plate is underneath the microscope slide (Fig. 1 elements 7 & 9) that can be used to heat the sample on the slide (col. 6 lines 5-8). The heater plate protects the heating element from any spillage of the liquid from the slide (col. 6 lines 11-12) and with the heat transfer into the fluid observation system being through the heating plate (col. 6 lines 13-14), thus the heating plate is integrated into the microscope slide. For claim 10, the heater plate of Loeffler is connected to a resistive heating element (**heating is electrical heating**) (col. 6 line 10) that facilitates even heat transfer across the plate. At the time of the invention, it would have been obvious to one of ordinary skill in the art to

employ the heater plate and heating element as suggested by Loeffler within the teachings of Barnes in order to heat the sample within the chamber. The suggestion for doing so at the time would have been in order to stabilize the temperature around a desired mean temperature (col. 6 lines 16-17).

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The art taught by Cremonese (U.S. 4,839,292) discloses a cell culture flask utilizing a membrane barrier that is attached to the housing via a retaining ring. Also, Focht (U.S. 4,974,952) discloses a live cell chamber for monitoring micro-organisms that includes a thermistor and external means to heat the chamber such as a Peltier element or a electro-resistive heating element. Another device for testing of a sample on a slide includes the art taught by Han et al. (U.S. 6,706,520) which discloses an apparatus for the assessment of the invasive potential of tumor cells where the device includes using a porous membrane with a transparent plate as a base member. McDevitt discloses a method and apparatus for the delivery of samples to a chemical sensor array that includes a transparent cover that can be made of either plastic, glass, quartz or silicon dioxide/silicon nitride.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL L. HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mikhail Kornakov can be reached on (571) 272-1303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLH

/Michael Kornakov/

Supervisory Patent Examiner, Art Unit 4151